Package leaflet: Information for the patient

Cuprior 150 mg film-coated tablets
trientine

You can find the information also when flashing the QR code below with a smartphone or via the website *QR code to be included* http://www.cuprior.com

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take Cuprior
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1. What Cuprior is and what it is used for

Cuprior is a medicine used to treat Wilson's disease that contains the active substance trientine.

Wilson's disease is an inherited condition in which the body cannot transport copper around the body in the normal way or remove copper in the normal way as a secretion from the liver into the gut. This means that the small amounts of copper from food and drink build up to excessive levels and can lead to liver damage and problems in the nervous system. This medicine mainly works by attaching to copper in the body which then allows it to be removed in the urine instead, helping to lower copper levels. It may also attach to copper in the gut and so reduce the amount taken up into the body. Cuprior is given to adults, adolescents and children aged 5 years and over who cannot tolerate another medicine that is used to treat this disease, called penicillamine.

2. What you need to know before you take Cuprior

Do not take Cuprior
If you are allergic to trientine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Cuprior.

If you were already taking another trientine medicine, your doctor may modify your daily dose, the number of tablets or the number of intake in the day when switching to Cuprior treatment.

Your symptoms may initially get worse after starting the treatment. If this happens, you must tell your doctor.

Your doctor will regularly check your blood and urine to ensure that you receive the right dose of Cuprior to properly control your symptoms and copper levels.

You should tell your doctor if you get any side effects as this may indicate that your dose of Cuprior needs to be adjusted up or down.

This medicine may also reduce the level of iron in your blood and your doctor may prescribe iron supplements (see section "Other medicines and Cuprior" below).

If you have kidney problems, your doctor will regularly check that the treatment dose is appropriate and does not affect the functioning of your kidney.

The association of trientine with another medicine that contains zinc is not recommended.

Lupus-like reactions (symptoms may include persistent rash, fever, joint pain, and tiredness) have been reported in some patients switched to trientine medicine after penicillamine medicine. However it was not possible to determine if the reaction was due to trientine or to previous penicillamine treatment.

Children and adolescents
Your doctor will carry out checks more frequently to ensure your copper levels are maintained at a suitable level for normal growth and mental development.
This medicine is not recommended for children aged below 5 years of age.

Other medicines and Cuprior
Tell your doctor if you are taking, have recently taken, or might take any other medicines.

In particular, you must tell your doctor if you are already taking iron supplements or if you take indigestion remedies (medicines that reduce discomfort after eating). If you take these medicines you may need to take Cuprior at a different time in the day because otherwise Cuprior may not be as effective. If you take iron supplements, make sure that at least two hours have passed between taking Cuprior and taking your iron supplements.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

It is very important to continue treatment to reduce copper during pregnancy. You and your doctor should fully discuss the potential benefits of treatment whilst considering any possible risks that there may be. Your doctor will advise you which treatment and which dose is best in your situation.

If you are pregnant and taking Cuprior, you will be monitored throughout your pregnancy for any effects on the baby or changes in your copper levels. When your baby is born, the copper level in the baby's blood will also be monitored.

It is not known if Cuprior can pass into breast milk. It is important to tell your doctor if you are breast-feeding or plan to do so. Your doctor will then help you decide whether to stop breast-feeding or to stop taking Cuprior, considering the benefit of breast-feeding to the baby and the benefit of Cuprior to the mother. Your doctor will decide which treatment and which dose is best in your situation.

Driving and using machines
Cuprior is not expected to affect your ability to drive a car or use any tools or machines.

3. How to take Cuprior

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

In adults of all ages, the recommended total daily dose is 3 to 6½ tablets per day (making a total of between 450 and 975 mg). This daily total will be divided into 2 to 4 smaller doses to be taken during the day. Your doctor will tell you how many tablets you should take and how often in the day. Tablets can be divided in half if needed.

Use in children and adolescents
The dose that you will take is usually lower than for an adult and depends on your age and body weight.
The usual total daily dose is between 225 and 600 mg (1½ to 4 tablets daily), which will be divided into 2 to 4 smaller doses to be taken during the day. Your doctor will tell you how many tablets you should take and how often in the day.

Once you have started the treatment, your doctor may adjust the dose based on the response to treatment.

Swallow the tablets with water on an empty stomach, at least one hour before meals or two hours after meals and at least one hour apart from any other medicines, food, or milk.

If you take iron supplements, take them at least two hours after taking a dose of Cuprior.

If you take more Cuprior than you should
Take Cuprior only as it is prescribed for you. If you think you may have taken more Cuprior than you were told to, contact your doctor or pharmacist.

If you forget to take Cuprior
Do not take a double dose to make up for a forgotten dose. Just take your next dose at its regularly scheduled time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you stop taking Cuprior
This medicine is for long-term use. Do not stop your treatment without the advice of your doctor even if you feel better because Wilson's disease is a life-long condition.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported:

Common (may affect up to 1 in 10 people)
- feeling sick (nausea)

Uncommon (may affect up to 1 in 100 people)
- skin rashes
- itching
- anaemia

Not known (frequency cannot be estimated from available data)

- stomach upsets and discomfort, including severe stomach pains (duodenitis)
- inflammation of the gut which may lead to e.g. abdominal pain, recurring diarrhoea and blood in stools (colitis)
- decrease in the number of red blood cells due to low iron level in your blood (iron deficiency anaemia)
- urticaria (nettle rash or hives).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

United Kingdom:
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland:
HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cuprior

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cuprior contains
The active substance is trientine. Each film-coated tablet (tablet) contains trientine tetrahydrochloride equivalent to 150 mg trientine.
The other ingredients are:
Tablet core: mannitol, colloidal anhydrous silica and glycerol dibehenate.
Tablet film-coating: polyvinyl alcohol, talc, titanium dioxyde (E171), glycerol monocaprylocaprate (Type I), iron oxide yellow (E172) and sodium laurilsulfate

What Cuprior looks like and contents of the pack
Yellow, 16 mm x 8 mm oblong film-coated tablet with a score line on each side. The film-coated tablet can be divided into equal doses.

OPA/Alu/PVC-Alu blisters, each blister contains 8 film-coated tablets. Cuprior is available in packs containing 72 or 96 film-coated tablets.
Not all pack sizes may be marketed.

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Orphalan

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Manufacturer
Delpharm Evreux
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Other sources of information
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu. There are also links to other websites about rare diseases and treatments.